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Manufactured for NovoNordisk by  
 Ben Venue Laboratories, Inc.  
 300 Northfield Road  
 Bedford, OH 44146  
 Telephone: (800) 562-4797  
 -or- (440) 232-3320

## MATERIAL SAFETY DATA SHEET

### Section I - IDENTITY

**Common/Trade Name:** GlucaGen® 1mg/lyophilized  
**Chemical Names:** Peptide C<sub>153</sub>H<sub>225</sub>N<sub>43</sub>O<sub>49</sub>S  
**Synonyms:** Glucagen (rDNA origin) for Injection  
**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.  
**Address:** 300 NORTHFIELD ROAD  
 BEDFORD, OH 44146  
**Emergency Telephone Number:** Chemtree: 1(800) 424-9300  
**Telephone Number for Info.:** (440) 232-3320 or (800) 562-4797  
**Medical Emergency: Professional Services:** 1(800) 521-5169  
**Date Prepared:** September 30, 1999  
**Date Revised:** December 18, 2001  
**Date Revised:** July 20, 2004  
**Date Revised:** July 16, 2007

### Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

Component	%	CAS#	OSHA PEL	ACGIH TLV	Other Limits Recommended
Glucagen (rDNA origin)	0.93%	NONE	NONE	NONE	NONE
Lactose Monohydrate	99.07%	5989-81-1	NONE	NONE	NONE

Glucagen is a sterile parenteral injectable drug presented as a powder cake. It must be reconstituted with Sterile Water for Injection prior to administration.

### Section III - HEALTH HAZARD DATA

**Routes of Entry:** Glucagen may be absorbed through inhalation of aerosols and skin contact.  
 Exposure is not expected under normal use.

**Health Hazard (Acute & Chronic):** Glucagen is a drug used to treat severe hypoglycemia (low blood sugar) in diabetic patients treated with insulin. Product affects the gastrointestinal system and liver.

**Carcinogenicity:** NTP? NO IARC Monographs? NONE  
 OSHA Regulated? NO

**Signs & Symptoms of Exposure:** Product is an antihypoglycemic agent and acts to slow gastrointestinal activity. Signs/symptoms of exposure are minimal. A person may exhibit a rapid heart rate and nausea and vomiting. May increase blood pressure.

**Medical Conditions Generally Aggravated by Exposure:** Persons who have pheochromocytomas; may cause allergic reaction in sensitive persons.

**BVL Hazard Category:** 1

#### Section IV - FIRST AID MEASURES

**Eye Exposure:** Flush eyes with water.

**Skin Exposure:** Wash skin with soap and water.

**Ingestion:** Do not induce vomiting. Seek medical attention from physician immediately.

**Inhalation:** If difficulty breathing, administer oxygen. Seek medical attention immediately.  
If necessary, provide artificial respiration.

#### Section V - FIRE AND EXPLOSION HAZARD DATA

**Flash Point (Method Used):** Not determined

**Flammable Limits:** Glucagen is not flammable

**LEL:** NA **UEL:** NA

**Extinguishing Media:** Use water or an ABC dry chemical fire extinguisher.

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard.

**Unusual Fire/Explosion Hazards:** None

#### Section VI - ACCIDENTAL RELEASE INFORMATION

**Release to Land:** Wet Glucagen with water and absorb with absorbent materials; dispose of according to local, state, and federal regulations.

**Release to Air:** If dust is generated, avoid and reduce exposures by ventilating area; clean up spill immediately.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; however, refer to local, state, and federal guidelines.

#### Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE

**Steps to be taken in case material is released or spilled:** See Section VI above. Wear latex or nitrile gloves and safety glasses when cleaning spills. A dust/mist respirator (N95) may be necessary if excessive dusts are generated.

**Waste Disposal Method:** Incinerate in an approved/permitted incinerator is recommended. Refer to federal, state, and local rules.

**Precautions to be taken in handling and storing:** Store in refrigeration between 2-8°C (36-46°F)  
Avoid freezing and protect from light.

**Other Precautions:** None

#### Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT



**Respiratory Protection:** Under normal use, respiratory protection is not required. If dusts are generated, use a disposable dust/mist respirator (N95). Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

**Ventilation:** Handle product in a well-ventilated area.

**Protective Gloves:** Nitrile or latex

**Eye Protection:** Safety glasses

**Other Protective Clothing or Equipment:** None

**Work/Hygienic Practices:** Wash hands prior to and following use. No eating, drinking, or smoking while handling product.

#### Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

**Physical State:** Solid

**Appearance and Odor:** White powder with no odor

**Boiling Point:** Not Applicable

**Vapor Pressure:** Not Applicable

**Vapor Density:** Not Applicable

**Specific Gravity:** Not Applicable

**Melting Point:** Not Available

**Evaporation Rate:** Not Applicable

**Solubility in Water:** >0.1%

**pH:** Not Applicable

(When reconstituted, forms a solution with a pH of 2.5-3.5)

#### Section X - STABILITY AND REACTIVITY DATA

**Stability:** None

**Incompatibility (Materials to Avoid):** None

**Hazardous Decomposition or Byproducts:** May emit toxic fumes when heated to combustion. As with any fire carbon monoxide and carbon dioxide or other toxic gases may be produced.

**Hazardous Polymerization:** Will not occur.

**Conditions to Avoid:** None

#### Section XI - TOXICOLOGICAL INFORMATION

LD<sub>50</sub> subcutaneous and intravenous, rats and mice > 100 mg/kg

#### Section XII - ENVIRONMENTAL IMPACT INFORMATION

Information is currently not available on the environmental impact of Glucagen. Handle in a manner to prevent spills or releases to the environment.

#### Section XIII - DISPOSAL INFORMATION

Dispose of by incineration at an approved/permitted incinerator.

Review local, state, and federal regulations.

#### Section XIV - TRANSPORTATION INFORMATION

Glucagen is not a D.O.T. Hazardous Material.  
Glucagen is not a Marine Pollutant

#### Section XV. REGULATORY INFORMATION

SARA 313 listed?: NO  
CERCLA listed?: NO  
RCRA listed?: NO

#### Section XVI. OTHER DATA

1. Use of this product should be through or under the direction of a physician. This MSDS does not address the therapeutic use of this material.
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):  
1 = Low Toxicity  
2 = Moderate Toxicity  
3 = Potent or Toxic  
4 = Highly Potent or Toxic  
5 = Extremely Potent or Toxic
4. OEL=Occupational Exposure Limit. An internal limit set by Ben Venue Laboratories for the recommended limit of employee exposure to airborne dusts or aerosols that should not be exceeded over an eight-hour time-weighted average.

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